UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,023	08/06/2001	Tor Regberg	PU-9843	6811

22840 7590 11/03/2004

AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/869,023
Filing Date: August 06, 2001
Appellant(s): REGBERG ET AL.

Royal N. Ronning, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/28/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-8 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ligands #1, 2, 5, 7, 10, 11, and 14 does not reasonably provide

enablement for ligands #3, 4, 6, 8, 9, 12 and 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1-8 are drawn to a method for selectively enriching/removing a serum albumin from a mixture of other compounds by contacting said mixture with a ligand (=X). The said ligand having affinity for and enabling binding of the serum albumin. The instant specification recites 14 ligand structures, see pages 13-14. The instant specification recites 3 test proteins, see page 14, lines 2-4. As best understood, the results of the binding recite that based on conventional ways of interpreting the chromatogram recorded, none of the ligand structures showed binding to IgG or HSA (see page 16, lines 2-4). Further, the instant specification recites that all chromatograms for IgG looked the same and the position of the eluted IgG suggested no interaction/binding (see page 16, lines 9-11). Accordingly, based upon the apparent results set forth, e.g., on pages 15-16 of the instant specification with respect to the non-binding of albumin to the disclosed/ claimed ligand structures, the claimed invention is not deemed enabled.

It is agreed that 7 ligands (# 1, 2, 5, 7, 10, 11, and 14) are enabled because the instant specification demonstrates an interaction with the media and there is no reason to doubt the accuracy of the instant specification. However, the instant specification does not enable one to determine which other ligands encompassed by the claims are effective. The instant specification indicates that none appeared effective when analyzed by conventional techniques. The efficacy of the 7 (# 1, 2, 5, 7, 10, 11, and 14) was only determined when appellants "went further" than conventional analysis of chromatograms (see page 16, line 6). The instant specification does not provide guidance on how to conduct this "further analysis". No indication of how the analysis

was conducted- is there a computer algorithm? Chromatogram analyzed by eyeballing? There is no drawing to illustrate what the chromatogram looked like to indicate ligand binding. The instant specification says tailing, small peaks when the column re-equilibrated, etc.- does not say how it was determined this interaction was "real" and not the result of a poorly packed column, contamination, etc., which can also cause tailing and spurious peaks. The instant specification does not say how the peaks were detected- (UV absorbance, immunoassay for albumin, some other method?).

The nature of the invention is drawn to methods of purifying serum albumin using novel compounds alleged to specifically bind serum albumin.

The breadth of the claims is excessively broad. An estimate of how many ligands are encompassed by the instant claims might be at least several thousand.

The predictability of the art is unpredictable. There is no way to predict which ligand will work, at least as disclosed by the instant specification.

The amount of guidance provided in the instant specification is little to none, for reasons above.

The working examples are of ligands which the appellants say worked, but it is not clear how it was determined the ligands work, since appellant admittedly did not use conventional analytical methods to make the determination.

The amount of experimentation required is considerable, considering the ligands must be synthesized and coupled to packing material, then the results must be analyzed (how?).

Given the above, it is concluded that it would require undue experimentation to use the methods with ligands other than those that the instant specification states are effective.

(11) Response to Argument

Appellant points to experimental results on pages 16-17 of the instant specification. Specifically, as stated on page 16, structures 1-14 were tested for binding HAS in PBS at pH 7 and 7 structures (# 3, 4, 6, 8, 9, 12, and 13) showed an HAS peak located at the same elution volume and having the same shape. The other structures (# 1, 2, 5, 7, 10, 11, and 14) demonstrated an interaction with the media which is apparent from the shoulders and tailing of the peaks. Appellants assert this demonstrates that such compositions are useful for enriching/ removing a serum albumin from a mixture of other compounds, and further, that such analyses of the chromatograms are known and practiced by those skilled in the art. However, the examiner contends that the appellant's instant specification did something not conventional in the art (see page 16, line 6). Appellant's brief states such analyses of the chromatograms are known and practiced by those skilled in the art, however, the instant specification states that based on conventional ways of interpreting the chromatogram recorded, none of the ligand structures showed binding to IgG or HAS. The instant specification is enabled for the 7 structures (#1, 2, 5, 7, 10, 11, and 14) that demonstrated an interaction with the media, apparent from the shoulders and tailing of the peaks, regardless of how appellant came to that conclusion. However, undue experimentation is required for the other 7 structures (# 3, 4, 6, 8, 9, 12, and 13) because no adequate guidance is provided or explanation given, nor does the brief contain evidence to support how to use the invention because interaction is so weak it cannot be practiced by one of ordinary skill in the art without undue experimentation.

For the above reasons, it is believed that the rejection should be sustained.

Respectfully submitted,

Roy Teller

October 22, 2004

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

JON WEBER
SUPERVISORY PATENT EXAMINER

Royal N. Ronning, Jr.

Amersham Biosciences Corp.

800 Centennial Avenue

P.O. Box 1327

Piscataway, New Jersey 08855-1327